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DEC 17 1992

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fisher's Lane, Room 11-44
Rockville, MD 20857

Dear Mr. Wilson:

The enclosed application for extension of the patent term of U.S. Patent No. 4,486,425 issued on December 4, 1984, was filed on December 7, 1992, under 35 USC § 156.

Your assistance is requested in confirming that the product identified in the application has been subject to a regulatory review period within the meaning of 35 USC § 156 (g) before its commercial marketing or use. Since a determination has not been made whether the patent in question claims a product which is subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 USC § 156 (d) (2) (A).

Your attention is directed to Paragraph No. 5 of the application wherein applicant notes that the application was not filed within the sixty - day period beginning on the date the product received permission for commercial marketing or use.

C. E. Van Horn

Charles E. Van Horn
Patent Policy & Projects Administrator
Office of the Assistant Commissioner for Patents

cc: Lawrence T. Welch
Corporate Intellectual Property Law
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